(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
7 February 2002 (07.02.2002)

PCT

(10) International Publication Number
WO 02/09594 A2

(51) International Patent Classification[7]: A61B 17/11

(21) International Application Number: PCT/NO01/00325

(22) International Filing Date: 30 July 2001 (30.07.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/222,051 31 July 2000 (31.07.2000) US

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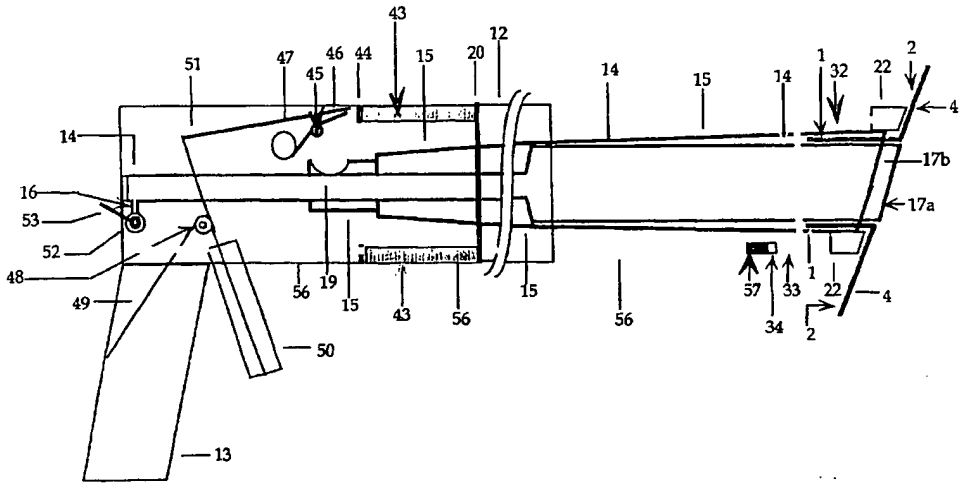
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AT (utility model), AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, CZ (utility model), DE, DE (utility model), DK, DK (utility model), DM, DZ, EC, EE, EE (utility model), ES, FI, FI (utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (utility model), SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: DEVICE, APPARATUS, AND PROSTHESIS FOR SUTURLESS ANASTOMOSIS



(57) Abstract: The invention concerns a device for temporary coupling an anastomosis prosthesis to an anastomosis apparatus, a deployment apparatus and a prosthesis for performing suturless anastomosis. Coupling of the anastomosis prosthesis to the coupling device is performed by suction and coupling of the coupling device to the deployment tube is performed by a fixation and a fastening mechanism.

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Device, apparatus, and prosthesis for suturless anastomosis

Related Application

The patent application claims priority from United States Provisional Patent Application Serial No. 60/222,051 filed on July 31, 2000, the entire disclosure of the application being expressly incorporated herein by reference.

Technical Field

The invention disclosed in the patent application concerns a device for temporary coupling an anastomosis prosthesis to a deployment apparatus, a deployment apparatus and a prosthesis for suturless anastomosis, and methods for using the said devices for the said purpose.

Background Art

A simple method for joining one hollow organ end-to-side to another hollow organ, without interrupting fluid follow in the efferent organ has long been desired in the medical practice, particularly in the field of cardiovascular surgery. Conventional methods for joining (anastomosing) two blood vessels in an end-to-side configuration invariably necessitates halting blood flow in the efferent or outflow blood vessel, jepoardising the viability of tissues perfused by the outflow blood vessel. To overcome this drawback, a surgical technique has been described in medical literature that involves the stitching of a metal ring to the outflow vessel (Tulleken CAF, et. al. Acta Neurochir 1995; 134:66-70), and a tubular prosthesis to the inflow or afferent limb of the anastomosis. The later is stitched to the metal ring, and luminal continuity established with the help of optical energy transmitted by a catheter passed through the tubular prosthesis. The complexity of the procedure has hindered its adoption by surgeons.

Hence the use of a biocompatible adhesive instead of stitches has been advocated and devices exploiting the idea have been disclosed in PCT/NO99/00093.

The present invention extends this concept further by providing the means for implanting a prosthesis on a blood vessel without the need for manipulation of the blood vessel, making performance of remote-controlled, robot-assisted vascular anastomosis a clinically realistic proposition.

The device for temporary coupling an anastomosis prosthesis to an anastomosis apparatus according to the invention comprises:
- a ring shaped member consisting of at least one ring section, wherein each ring section comprises at least one radial partition walls defining at least two chambers, and a common upper chamber limited by a section roof, wherein the chambers are adapted for aposing to the anastomosis prosthesis and fastening to said prosthesis by means of a suction pressure, wherein the common upper chamber provides a channel in fluid connection with the chambers,
- a tubing connection assembly in fluid connection with said channel for transmitting a suction pressure from a suction apparatus to the chambers, and
- a fixation mechanism for fastening the ring shaped member to an anastomosis apparatus. The coupling device is thus meant for attachment to the prosthesis by suction, where the floor of the at least one section is apposed to the prosthesis.

There are several alternative ways of fastening the coupling device to the anastomosis apparatus, but all embodiments have the common feature that they permit easy, secure and precise fastening of these parts together.

The invention comprises also an anastomosis apparatus which in one embodiment comprises a coupling device that is an integrated part of the apparatus. In this case the fixation mechanism in the coupling device is not adapted for temporarily attachment to the apparatus.

Back to the coupling device, in a first embodiment of the invention the coupling device comprises a fixation mechanism with:
- an attachment plate with a rectangular projection or offset block, the attachment plate and the offset block being perforated, and
- a threaded fixation pin through the attachment plate and the offset block, where the pin is provided on or in the vicinity of one end with a nut and on or in the vicinity of the other end with a fixation plate,
- where the offset block and the fixation plate are meant to be tightened against an outer and an inner surface respectively in a deployment tube in the apparatus by means of the pin.

In a second embodiment of the invention the fixation mechanism comprises:
- an attachment plate with a rectangular projection or offset block, and
- a fixation pin extending between the offset block and a fixation plate,

- where the offset block and the fixation plate are meant to be arranged against an outer and an inner surface respectively in a deployment tube in the apparatus.

In a third embodiment the fixation mechanism comprises:
- a torsion spring, where one limb of the torsion spring is attached to the fixation plate and the other limb is accommodated in a groove in the offset block,
- where the torsion spring is meant for pushing the fixation pin into a fixation slot in a deployment tube in the fixation apparatus.

In a fourth embodiment the fixation mechanism comprises a bent resilient wire in stead of a torsion spring, where one limb of the wire is attached to the fixation plate and the other limb is accommodated in a groove in the offset block, where the resilient wire is meant for pushing the fixation pin into a fixation slot in a deployment tube in the fixation apparatus.

In a fifth embodiment the fixation mechanism comprises:
- an attachment plate with a rectangular projection or offset block, and
- a polymer hook or loop patch bonded to the offset block,
- where the hook patch is meant for fastening the offset block to a corresponding polymer loop or hook patch on a deployment tube in the anastomosis apparatus.

In a sixth embodiment the fixation mechanism comprises:
- an attachment plate with a rectangular projection or offset block, and
- a flat magnet bonded to the offset block,
- where the flat magnet is meant for fastening the offset block to at least one corresponding ferromagnetic patch on a deployment tube in the anastomosis apparatus.

In a preferred embodiment of the invention the chambers are provided with a mesh on the surface adapted for aposing to the anastomosis prosthesis.

As stated before the invention also includes a deployment apparatus for suturless anastomosis between two hollow organs by means of an implantable anastomosis prosthesis and a prosthesis coupling device comprising:
- a targeting tube,
- a deployment tube provided with a fastening device for cooperation with a fixation mechanism in the prosthesis coupling device, for fastening said prosthesis coupling device to said deployment tube,
- a flow control valve for controlling fluid flow in and out of the apparatus, wherein the inlet of the valve is adapted for connection to a suction apparatus, and a first outlet of the valve is coupled to a fluid connecting device adapted for connection to a corresponding tubing conenction assembly in the anastomosis

coupling device,
- a flow control lever for controlling flow through said valve, and
- a trigger for displacing the deployment tube in relation to the body of the apparatus,
- a device for connecting the apparatus to a suction apparatus.

As one can see, the apparatus according to the invention has a targeting tube that permits a precise localisation of the apparatus at the anastomosis site, a deployment tube for receiving the coupling device and thus the prosthesis, and two triggering/control devices for controlling on one side suction pressure to be exerted by the coupling device against the anastomosis prosthesis and on the other side the movement of the prosthesis towards the anastomosis site. In one embodiment the targeting tube is adapted for applying suction to the organ to be anastomosed, thereby securing a stationary location of the apparatus. In another embodiment the apparatus is adapted for apposing the anastomosis prosthesis to the target organ with positive pressure.

In a first embodiment of the apparatus, adapted for use together with the first to fourth embodiments of the coupling device, the fastening device consists of at least one fixation slot extending from the edge of the deployment tube.

In a second embodiment of the apparatus, specially adapted for use together with the second embodiment of the coupling device each fixation slot comprises a long limb, a fixation fluke, a transverse limb and a short limb,
where the fixation fluke is meant for securing a fixation pin in a fixation mechanism in the prosthesis coupling device into the short limb of the fixation slot.

In a third embodiment of the apparatus, specially adapted for use together with the third embodiment of the coupling device each fixation slot comprises a long limb, a transverse limb and a short limb, where the short limb is meant for receiving a fixation pin in a fixation mechanism in the prosthesis coupling device.

In a fourth embodiment of the apparatus, adapted for use together with the fifth embodiment of the coupling device the fastening device consists of at least one loop or hook polymer patch arranged on the deployment tube for fastening to a corresponding hook or loop patch in a fixation mechanism in the prosthesis coupling device.

In a fifth embodiment of the apparatus, adapted for use together with the sixth embodiment of the coupling device the fastening device consists of at least one

ferromagnetic patch arranged on the deployment tube for fastening to a corresponding magnet in a fixation mechanism in the prosthesis coupling device.

In a preferred embodiment, the apparatus comprises an inlet for introduction of imaging or flow measuring devices.

As stated before, in another preferred embodiment of the invention the second outlet of the flow control valve is coupled to the inside of the targeting tube for transmitting a suction pressure to said targeting tube.

In another embodiment the apparatus comprises a prosthesis coupling device according to the invention as an integrated element of the apparatus.

The invention also includes an implantable anastomosis prosthesis comprising a first tubular member to be placed around a first organ, and a flat sheet or attachment member to be placed on a second organ, wherein the luminal or inner surface of the tubular member is continuous with the surface of the flat member facing the second organ. The prosthesis according to the invention comprises a second tubular member attached to the first tubular member for facilitating insertion of an anastomosis instrument in the prosthesis.

Use of the apparatus according to the invention will now be described briefly:

1) The coupling device is attached to the deployment tube,

2) the targeting tube is introduced into the side-arm of the anastomosis prosthesis,

3) the prosthesis is slid up the targeting tube till the prosthesis flat member abuts the coupling device,

4) the coupling device is fastened to the prosthesis,

5) the apparatus is introduced into the body and the tip of the targeting tube is placed at the chosen side for anastomosis,

6) the triggering device is pressed activating the actuator, and the deployment tube is longitudinally displaced along the targeting tube towards the organ, thereby delivering the mounted anastomosis prosthesis to the organ,

7) the anastomosis prosthesis is pressed against the organ,

8) the coupling device is detached from the anastomosis prosthesis.

As one can see the coupling device permits temporary coupling the prosthesis to the deployment tube. This temporary coupling is performed by establishing suction pressure between the coupling device and the prosthesis. When the prosthesis is in

place, the suction pressure is eliminated and the prosthesis is no longer fastened to the coupling device. In a further preferred embodiment of the invention the pressure is increased after the prosthesis is in place and thus the coupling device is used as a means for pressing the anastomosis against the organs.

The apparatus according to the invention combines pure a mechanical part for delivering the prosthesis to the anastomosis site and a fluid driven part for fastening the coupling device to the prosthesis, optionally fastening the targeting tube to the organ and in a preferred embodiment pressing the prosthesis against the organ.

The various embodiments of the invention will now be described with reference to the attached drawings, where:

Fig. 1 is a perspective view of a first embodiment of the anastomosis prosthesis.

Fig. 2 is a longitudinal section of the embodiment in figure 1 along long axis of side-arm.

Fig. 3 is a perspective view of a second embodiment of the anastomosis prosthesis.

Fig. 4 is a perspective view and a partial cut of a third embodiment of the anastomosis prosthesis.

Fig. 5 is a perspective view of a fourth embodiment of the anastomosis prosthesis.

Fig. 6 is a longitudinal section of said fourth embodiment of anastomosis prosthesis along long axis of side-arm.

Fig. 7 is a perspective view of a fifth embodiment of the anastomosis prosthesis according to the present invention.

Fig. 8 is a longitudinal section of said fifth embodiment of anastomosis prosthesis along long axis of side-arm.

Fig. 9 is a perspective view of an embodiment of apparatus according to the invention.

Fig. 10 is a longitudinal section of said embodiment of the apparatus.

Fig. 11 is a transverse cross section (through spring compression plate) of preferred (first) embodiment of instrument.

Fig. 12 is a cross-section (through first and second outlet ports) of a 3-port valve in a first position.

Fig. 13 is a cross-section (through first and second outlet ports) of the 3-port valve in figure 12 in a second position.

Fig. 14 is a longitudinal section (through first and second outlet ports) of the 3-port valve in figure 12 in the second position.

Fig. 15 is a cross-section of the coupling device through suction chambers.

Fig. 16 is a cross-section of the coupling device through free edges.

Fig. 17 is a longitudinal para-tangential section of the coupling device through three adjacent suction chambers.

Fig. 18 is a longitudinal section of the apparatus, the coupling device and the prosthesis according to the invention and shows the fluid circuit.

Fig. 19 is a longitudinal radial section of the coupling device through fixation screw and connection plug.

Fig. 20 is a cross-section through fixation screw of attachment plate of the coupling device.

Fig. 21 is a longitudinal section of the coupling device through fixation screw.

Fig. 22 is a cross-section of the coupling device through attachment plates.

Fig. 23 is a perspective view of a first embodiment of free end of deployment tube.

Fig. 24 is a longitudinal section (through fixation pin) of fixation plate of coupling device mounted on deployment tube.

Fig. 25 is a cross-section (through fixation pin) of fixation plate of coupling device hood mounted on deployment tube.

Fig. 26 is a longitudinal section of a preferred embodiment of the apparatus carrying two suction hoods.

Fig. 27 is a longitudinal cross-section of a preferred embodiment of the apparatus (carrying two suction hoods) with trigger pressed.

Fig. 28 is a longitudinal section of the attachment plate through fixation pin in a second embodiment of the coupling device.

Fig. 29 is a perspective view of the free end of the deployment tube in a second embodiment of the apparatus.

Fig. 30 is a longitudinal section of the attachment plate through torsion spring in a third embodiment of the coupling device.

Fig. 31 is a cross-section of the attachment plate along the free end of the torsion spring in said third embodiment.

Fig. 32 is a perspective view of the free end of deployment tube in a third embodiment of the apparatus.

Fig. 33 is a longitudinal cross-section (through torsion spring) of fixation plate of a suction hood mounted on the deployment tube.

Fig. 34 is a longitudinal radial section (through fixation pin) of a fifth and a sixth embodiment of the coupling device mounted on the deployment tube.

Fig. 35 is a perspective view of the free end of deployment tube of a fifth embodiment of the apparatus.

Fig. 36 is a perspective view of free end of the deployment tube in another embodiment of the apparatus.

Detailed description of a preferred embodiment of the invention:

Anastomosis prosthesis:

Figures 1 and 2 show a first embodiment of the anastomosis prosthesis for use in the present invention. In this embodiment the prosthesis comprises a tubular member (side-arm) 1 that is attached to a flat, pliable sheet (attachment member) 2 at an acute angle or at 90°, such that the luminal or inner surface 3 of the side-arm 1 is continuous with the far surface (attachment surface) 4 of the attachment member 2, that is the surface of the attachment member facing the second organ. An opening (ostium) 5 in the attachment member 2 matches the cross-sectional area of the lumen of the side-arm 1.

The attachment surface 4, or the luminal surface 3, or both are preferably lined with a biocompatible adhesive, or one or multiple pharmacologic agents or both.

Figure 3 shows a second embodiment of the prosthesis, wherein the end of the side-arm 1 continuous with the attachment member 2 is reinforced with a metal collar 6, that may have thermodynamic shape-memory.

Figure 4 shows a third embodiment of the prosthesis wherein the side-arm 1 is reinforced with a cylindrical mesh 7 of a metal with thermodynamic shape-memory.

Figures 5 and 6 show a fourth embodiment of the prosthesis. In this embodiment, the side-arm 1 is parallel to the attachment member 2, and has a side-hole 8, that is circumferentially continuous with the ostium or opening 5 in the attachment member 2.

Figures 7 and 8 show a fifth embodiment of the prosthesis. Here, a second tubular member (apparatus inlet) 9 is connected to the side-arm 1, such that the opening (apparatus port) 10 between the side-arm 1 and the apparatus inlet 9 projects on the ostium 5 along the long axis of the apparatus inlet 9.

The attachment member 2 is preferably provided with visual markers to help align the prosthesis satisfactorily with the organ.

Apparatus and coupling device

Figure 9 shows a first embodiment the apparatus according to the invention. It comprises an elongated part 11 with an assembly to carry the anastomosis prosthesis, and an outer casing (body) 12 incorporating a hand grip 13, that contains the trigger to deploy the anastomosis prosthesis and a flow control lever 53 for controlling flow in and out of the apparatus. Figure 9 shows also a fluid connecting device or female device 57 for connection between the apparatus and the prosthesis coupling device.

The elongated part 11 includes two sliding coaxial tubular members, an inner targeting-tube 14, and the deployment tube 15. The targeting tube 14 permits placement of the apparatus on the right position on one of the organs to be anastomosed, while the deployment tube 15 carries the prosthesis and moves it into place on said organ.

Referring now to figure 10 that shows a longitudinal section of the apparatus, the targeting-tube 14 runs the length of the apparatus and has a side-arm 16 near one end, this side-arm establishes a connection between a flow control valve 52 and the targeting tube. The flow control valve 52 as will be described later is adapted for coupling to a suction apparatus and a suction pressure can thus be transmitted vil side-arm 16 to the targeting tube 14 . For this purpose the end of the targeting-tube 14 near the side-arm 16 is fixed to the body 12 such that the attachment is impervious to the passage of air. The other end of the targeting-tube 14 protrudes from body 12, and its free-edge 17a is perpendicular to the longitudinal axis of the tube 14 or makes an acute angle with it.

The deployment tube 15 is shorter in length than the targeting-tube 14 and the free edge of its protruding end 17b is substantially congruent with the corresponding free edge 17a of the targeting-tube 14. At the opposite end of the deployment tube,

an upwards-facing circular recess 19 is present. Forward to the recess 19, the deployment tube 15 has a coaxial collar (spring-compression plate) 20 that can be seen in further detail in figure 11, which shows how compression plate 20 is fixed to the deployment tube 15 by two or more radial struts 21.

The body of apparatus 12 has the shape of a flattened cylinder which is closed at one end. An angulated extension near the closed-end serves as the hand-grip 13. A helical compression spring 43 is coaxially mounted between a narrow collar on the inner surface of the body (spring-retention collar) 44, and the spring-retention plate 20 of the deployment tube 15, distracting the retention collar 44 from the retention plate 20. Behind the spring-retention collar, is a pivot pin 45 supporting a substantially linear member (pivoting lever) 46. Fixed to the lower end of the pivoting lever 46 is a spherical member (weighting sphere) 47, whose weight applies counter-clockwise torque on the pivoting lever 46. The other end of the pivoting lever is in contact with the inner surface of the body 12 and is thereby restrained from free counter-clockwise rotation. Hinged via a pivot pin 48 to a pair of brackets in the hand-grip 13, and biased by a torsion spring 49, is a lever designed to accommodate the fingers (trigger) 50. A «L» shaped member, (trip lever) 51 extends from the trigger 50 within the lumen of the body 12, in the direction of the upper end of the pivoting lever 46. The body 12 is provided with a 3-port, 3-way valve 52, whose flow control lever 53 is accessible from outside the body 12 of the apparatus, the flow control lever 53 being the trigger of the fluid driven part of the apparatus.

Figures 12, 13 and 14 show valve 52 in closer detail. One outlet 54 of the valve 52 is connected to the sidearm 16 of the targeting-tube 14 as stated before. Another outlet 55 of the valve 52 is connected to a flexible tube (primary suction tube) 56, which ends in the female counterpart 57 of the male component 34 of the tubing connection assembly that permits coupling of the coupling device to the prosthesis in a way that will be described in detail later. The female component 57 of the tubing connection assembly is fixed to the deployment 15 tube near its free edge 17b. The inlet 58 of the valve is continuous with an external plug (suction plug) 59 that is suitable for connecting to a suction apparatus.

The function of the embodiment of the apparatus described above will be explained later in the description.

Figure 15 shows one embodiment of the coupling device according to the invention. This coupling device comprises a ring shaped member comprising of at least one, and in this case two ring sections or suction hoods 22, with similar radii of curvature. The coupling device can comprise more than two suction hoods 22 arranged in a circle as shown in the figure. Each suction hood 22 is divided into

multiple suction chambers 27 by radial partition walls 28. Figures 15 and 16 show that each suction hood 22 has parallel inner 23 and outer 24 walls, said walls being connected on one edge 25a, 25b by a mesh 26 in a preferred embodiment of the invention. As can be seen in figure 17, which shows a section of a suction hood 22, each suction hood 22 comprises a roof 29 which forms a ring shaped channel 30 communicating with each suction chamber 27 and thus establishing fluid connection between each chamber 27. Roof 29 (and thus ring shaped channel 30) are in fluid connection with a tubing connection assembly for transmitting a suction pressure from a connecting device to chambers 27. Said tubing connection assembly is shown schematically in figure 18 and comprises a linear plug 31 (connection plug) protruding from the roof 29 of the suction hood 22 coupled to channel 30. To plug 31 is attached a tube (tertiary suction tube) 32. The tertiary suction tubes from all suction hoods 22 of the ring shaped member open into a single tube (secondary suction tube) 33, which in turn ends in the male component 34 of the tube connection assembly. This male component 34 is the counterpart of the female component 57 mentioned with reference to figures 9 and 10. The fluid circuit is thus described in its entirety. Its function is to transmit a suction pressure from a suction apparatus (not shown) to suction hoods 22 so that these exert a suction pressure on the anastomosis prosthesis and hold it in place on the deployment tube 15.

The suction hoods 22 are mechanically fastened to deployment tube 15 by means of a fixation mechanism that will be described with reference to figures 19-21 which cooperates with a fastening device in the apparatus, which fastening device will be described with reference to figure 23. Figure 19 shows that at the apex of its curvature, the inner wall 23 of the suction hood 22 is continuous with a short rectangular plate (attachment plate) 35 that protrudes beyond the roof 29 of the hood 22. On the inner surface of the attachment plate 35 is a flat rectangular projection (offset block) 36. Figure 20 shows the offset block 36 with a concave free surface 37.

Figure 21 shows a first embodiment of the coupling device where a threaded fixation pin (fixation screw) 39 carrying a nut 40 passes perpendicularly through the attachment plate 35 and offset block 36. To the tip of the fixation screw 39 is attached a convex plate (fixation plate) 41, this figure shows the curvature of the attachment plate 35, offset block 36 and fixation plate 41.

Figure 22 shows the ring shaped member comprising two suction hoods 22 and the relative positions of linear plug 31 for fluid connection, and the fixation mechanism comprising fixation plate 41, offset block 36, fixation pin 39 and nut 40.

Figure 23 shows the edge 17b of deployment tube 15 in detail in a first embodiment of the apparatus. This figure shows the fastening device implemented as two or more short rectangular slots (fixation slots) 18 extending from the edge 17b which are arranged symmetrically around the circumference of the deployment tube 15. The aim of the fixation slots 18 is to provide a seat for introduction of fixation screw 39 in the coupling device for fastening the coupling device to the deployment tube 15.

Figures 24 and 25 show in detail the relative placement of suction hood 22 and deployment tube 15. Offset block 36 and fixation plate 41 are meant to be tightened against the outer 42 and the inner 38 surface respectively of the deployment tube 15 in the apparatus by means of the pin 39. In other words, the free surface 37 on offset block 36 is adapted for apposing against the outer surface of deployment tube 15 while the convex plate 41 is adapted to appose against the inner surface 42 of deployment tube 15.

The concept behind the invention can be realised in several ways as expressed by the various alternative of the invention. These alternative embodiments will be described in detail later.

Use of the invention will be now described by means of an example of the coupling device and the apparatus as described above and with reference to figures 22, 23, 24, 26 and 27.

Attachment of suction hood to apparatus:

Reference is now made to figures 22 and 23 and 24. A suction hood 22 with an appropriate radius of curvature in relation to the anastomosis prosthesis to be implanted is attached to the deployment tube 15. In this example, the fixation screw 39 of the suction hood 22 is introduced into a fixation slot 18 of the deployment tube 15, and advanced until it reaches the floor 73 of the slot. The nut 40 on the fixation screw 39 is turned clockwise until the fixation plate 41 is closely apposed to the luminal surface 42 of deployment tube 15, thereby securing the suction hood to the deployment tube 15. More suction hoods 22 are attached symmetrically to the deployment tube 15, the total number depending on the number of available fixation slots 18 and size of the anastomosis prosthesis.

Implantation of anastomosis prosthesis:

Reference will now be made to figures 7, 26 and 27. After the required number of suction hoods 22 are fixed to the deployment tube 15, the tertiary suction tubes are

connected to the secondary suction tube 33, and the latter is mated with the primary suction tube 56, the apparatus is cocked by manually drawing the deployment tube 15 towards the body 12 of the apparatus till the weighting sphere 47 engages the circular recess 19 (Fig. 26). A suction apparatus is connected to the suction plug 59 (not shown) on the 3-port valve 52. The targeting-tube 14 is introduced into the side-arm 1 or apparatus inlet 9 of an anastomosis prosthesis (Fig. 7), and advanced till the suction hoods 22 symmetrically abut the attachment member 2 of the prosthesis. The flow control lever 53 of the valve 52 is placed in position I (Fig. 26), establishing a channel between the suction apparatus and the primary suction tube 56. The suction apparatus is powered up creating negative pressure in the suction chambers 28, securing the anastomosis prosthesis to the apparatus. The free edge 17a of the targeting-tube 14 is placed at the desired site on the organ to be anastomosed, and aligned as appropriate. If deemed appropriate, an imaging device or a flow-measurement device may be introduced into the targeting-tube 14 through an inlet 70 (not shown) and the relevant data collected to confirm that the site selected for anastomosis is suitable. The flow-control lever 53 is placed in position II (Fig. 27), creating an open fluid circuit between the suction apparatus and the targeting-tube 14. Negative pressure is established in the targeting-tube 14, securing it to the organ. A biocompatible adhesive is applied to the tissue surfaces around the free edge 17a of the targeting-tube 14. This step may be skipped if the attachment surface 3 of the attachment member 2 is lined with an adhesive. The trigger 50 is pressed, rotating the trip lever 51 forwards (Fig. 27). The tip of the trip lever 51 rotates the pivoting lever 46, elevating weighting sphere 47. The compression spring 43 expands, driving the deployment tube 15 forwards, and apposing the attachment surface 4 of the anastomosis prosthesis to the organ to be anastomosed and the surrounding tissues. The flow-control lever 53 is placed in position I, and the pressure in the suction circuit is lowered further. After a firm adhesive bond has been established between the anastomosis prosthesis and the tissues, the suction apparatus is powered down. The flow control 53 lever is placed in position II, allowing the pressure in the suction circuit to return to atmospheric levels. The apparatus is removed from the body, leaving the anastomosis prosthesis attached to the organ.

Alternative embodiments of the invention and their use:

In an embodiment of the apparatus the suction hood 22 does not have a mesh 26. The advantage of this embodiment is that the absence of a mesh increases the suction force that is applied to the anastomosis prosthesis.

Figure 28 shows a second embodiment of the coupling device where the fixation mechanism comprises a short pin (fixation pin) 60 with the fixation plate 41 at its

tip. Figure 29 shows a second embodiment of the apparatus where the fastening device is implemented as fixation slots 18 comprising a long limb 74 for insertion of a fixation pin, a fixation fluke 74 to lock the fixation pin in place, a transverse limb 76 and a short limb 77. In this case, the fixation pin 60 is introduced into the long limb 74 of the fixation slot 18, and advanced till the fixation fluke 75 is displaced, opening the transverse limb 76 of the fixation slot 18. The suction hood 22 is revolved so that the fixation pin 60 advances along the transverse limb till it reaches the short limb 77 of the fixation slot 18. The suction hood 22 is released allowing the fixation fluke 75 to push the fixation pin 60 into the short limb 77 of the fixation slot 18, securing the suction hood 22 to the deployment tube 15.

Figures 30 and 31 shows a third embodiment of the coupling device where the fixation mechanism comprises fixation plate 41 and perpendicularly attached to this one limb of a torsion spring 61. The torsion spring 61 is coplanar with the long axis of the deployment tube 15. The offset block 36 in this embodiment has a linear groove 62 to accommodate the free end 63 of the torsion spring 61. Figure 32 shows a third embodiment of the apparatus. In this embodiment, the fixation slots 18 have a long limb 74, a traverse limb 76 and a short limb 77. In use, the fixation pin 60 is introduced into the long limb 74 of the fixation slot 18 and advanced till it reaches the transverse limb 76 of the slot 18. The suction hood 22 is revolved so that the fixation pin 60 advances along the transverse limb 76 till it reaches the short limb 77 of the fixation slot 18. The suction hood 22 is released allowing the torsion spring 61 to push the fixation pin 60 into the short limb 77 of the fixation slot 18, securing the suction hood 22 to the deployment tube 15 (figure 33).

In a fourth embodiment of the coupling device (figures 30, 31) the fixation mechanism comprises a resilient wire 64 bent at an acute angle. One end of the wire 64 is perpendicularly attached to the fixation plate 41, such that both limbs lie in a plane parallel to the long axis of the deployment tube 15. The offset block 36 has a linear groove 62 to accommodate the free end 65 of the resilient wire. In use, the fixation pin 60 is introduced into the long limb 74 (figure 32) of the fixation slot 18 and advanced until it reaches the transverse limb 76 of the slot 18. The suction hood 22 is revolved so that the fixation pin 60 advances along the transverse limb 76 till it reaches the short limb 77 of the fixation slot 18. The suction hood 22 is released allowing the free limb 65 of the resilient wire 64 to snap back to its original orientation, pushing the fixation pin 60 into the short limb of the fixation slot 18, securing the suction hood 22 to the deployment tube 15 (Fig. 33).

In case of the embodiment of the anastomosis prosthesis shown in figures 5 and 6, a modified version of the implantation procedure is used. The apparatus is not cocked. The anastomosis prosthesis is manually apposed against the end of the targeting-tube 14 such that the suction hoods 22 are symmetrically apposed to the attachment member 2, before the anastomosis prosthesis is hypobarically secured to the deployment tube 15 as explained above. The targeting-tube 14 is not hypobarically secured to the organ to be anastomosed. Nor is the anastomosis prosthesis mechanically deployed by pressing the trigger 50. Instead the anastomosis prosthesis is placed at the desired site, prior to reducing the pressure further in the suction circuit to ensure tight apposition between the attachment surface 4 of the anastomosis prosthesis and the underlying tissues.

Figure 34 shows a fifth embodiment of the coupling device where the suction hood 22 lacks a fixation screw 39 with plate 41. Instead, a polymer patch carrying multiple small, flexible, hooks (hook patch) 67 on its surface is bonded to the offset block 36. Figure 35 shows a fourth embodiment of the apparatus, where the fastening means are implemented by providing the outer surface 38 of the deployment tube 15 with two or more polymer patches carrying multiple small loops on its surface (loop patch) 66. The loop patches 66 are arrayed symmetrically around the circumference in the vicinity of the free edge 17b of the deployment tube 15. In use, the hook patch 67 on the offset block 36 is manually apposed to a loop patch 66 on the deployment tube 15, allowing the hooks to engage the loops, securing the suction hood 22 to the deployment tube 15.

In a sixth embodiment of the coupling device (figure 34) a flat magnet 69 is fixed to the offset block 36 of the suction hood 22. In a fifth embodiment of the apparatus (figure 35), the outer surface 38 of the deployment tube 15 is provided with two or more ferromagnetic patches 68. The ferromagnetic patches 68 are arrayed symmetrically around the circumference of the deployment tube 15, in the vicinity of its free edge 17b. In a preferred embodiment the surface of the magnet 69 has a pattern on it in bas relief which complements the pattern engraved on the ferromagnetic patch 68. In use, the magnet 69 on the offset block 36 is manually apposed to a ferromagnetic patch 68 on the deployment tube 15, securing the suction hood 22 to the deployment tube 15. In this embodiment of the apparatus, the magnet 69 on the offset block is manually apposed to a ferromagnetic patch 68 on the deployment tube 15, ensuring that the each ridge on the magnet 69 engages the corresponding groove on the ferromagnetic patch 68.

In a preferred embodiment of the apparatus the targeting-tube is provided with a inlet for the introduction of imaging or flow measurement devices. The inlet may

advantageously incorporate a valve for creating an airtight seal irrespective of whether or not an imaging or flow-measurement device is placed in the targeting-tube.

Figure 36 shows an embodiment of the apparatus, wherein the deployment tube **15** is provided with two or more long narrow slits **72** that are parallel to the long axis of the tube 15. The slits **72** are symmetrically arrayed around its circumference. These long narrow slits allow reversible splaying of the free end of the deployment tube **15** making it possible to attach coupling devices with radii of curvature substantially larger than the radius of the deployment tube 15 itself. This feature eliminates the need to dimensionally match the deployment instrument to the anastomosis prosthesis being deployed.

The combination of pressure-mediated attachment and release of the anastomosis prosthesis, with its mechanical deployment offers a number of advantages of relevance to the surgeon. The anastomosis prosthesis can be reversibly, yet securely, attached to the deployment instrument without the risk of damage associated with mechanical fixation. Release of the prosthesis after deployment does not involve the manipulation of movable members that may traumatise the target organ. The mechanical deployment mechanism allows for rapid, reliable single-handed delivery of the prosthesis to the target. As the coupling device carrying the prosthesis is detachable from the deployment instrument, the latter can be used with anastomosis prostheses of a wide range of sizes simply by matching the radius of curvature of the coupling device to the size of the anastomosis prosthesis.

Thus the invention allows accurate and reliable delivery of an anastomosis prosthesis to the chosen site on the target organ, which is a vital prerequisite to the performance of externally-supported non-sutured anastomosis.

PATENT CLAIMS

1. Device for temporary coupling an anastomosis prosthesis to an anastomosis apparatus, comprising:
- a ring shaped member consisting of at least one ring section (22), wherein each ring section (22) comprises radial partition walls (28) defining chambers (27), and a common upper chamber limited by a roof (29), wherein the chambers (27) are adapted for aposing to the anastomosis prosthesis and fastening to said prosthesis by means of a suction pressure, wherein the common upper chamber provides a channel (30) in fluid connection with the chambers (28),
- a tubing connection assembly (31-34) in fluid connection with said channel (30) for transmitting a suction pressure from a suction apparatus to the chambers (27), and
- a fixation mechanism for fastening the ring shaped member to an anastomosis apparatus.

2. Coupling device according to claim 1,
c h a r a c t e r i s e d i n that the fixation mechanism comprises:
- an attachment plate (35) with a rectangular projection or offset block (36), the attachment plate (35) and the offset block (36) being perforated, and
- a threaded fixation pin (39) through the attachment plate and the offset block (36), where the pin (39) is provided near one end with a nut (40) and near the other end with a fixation plate (41),
- where the offset block (36) and the fixation plate (41) are meant to be tightened against an outer (42) and an inner (38) surface respectively in a deployment tube (15) in the apparatus by means of the pin (39).

3. Coupling device according to claim 1,
c h a r a c t e r i s e d i n that the fixation mechanism comprises:
- an attachment plate (35) with a rectangular projection or offset block (36), and
- a fixation pin (60) extending between the offset block (36) and a fixation plate (41),
- where the offset block (36) and the fixation plate (41) are meant to be arranged against an outer (42) and an inner (38) surface respectively in a deployment tube (15) in the apparatus.

4. Coupling device according to claim 3,
c h a r a c t e r i s e d i n that the fixation mechanism comprises:
- a torsion spring (61), where one limb of the torsion spring is attached to the fixation plate (41) and the other limb (63) is accommodated in a groove (62) in

the offset block (36),
- where the torsion spring (61) is meant for pushing the fixation pin (60) into a fixation slot (18) in a deployment tube (15) in the fixation apparatus.

5. Coupling device according to claim 4,
characterised in that the fixation mechanism comprises:
- a bent resilient wire (64), where one limb of the wire (64) is attached to the fixation plate (41) and the other limb (65) is accommodated in a groove 62 in the offset block (36),
- where the resilient wire (64) is meant for pushing the fixation pin (60) into a fixation slot (18) in a deployment tube (15) in the fixation apparatus.

6. Coupling device according to claim 1,
characterised in that the fixation mechanism comprises:
- an attachment plate (35) with a rectangular projection or offset block (36), and
- a polymer hook or loop patch (67) bonded to the offset block (36),
- where the hook patch (67) is meant for fastening the offset block (36) to a corresponding polymer loop or hook patch (66) on a deployment tube in the anastomosis apparatus.

7. Coupling device according to claim 1,
characterised in that the fixation mechanism comprises:
- an attachment plate (35) with a rectangular projection or offset block (36), and
- a flat magnet (69) bonded to the offset block (36),
- where the flat magnet (69) is meant for fastening the offset block (36) to at least one corresponding ferromagnetic patch (68) on a deployment tube (15) in the anastomosis apparatus.

8. Coupling device according to any of the preceding claims,
characterised in that the chambers (27) are provided with a mesh (26) on the surface adapted for aposing to the anastomosis prosthesis.

9. Deployment apparatus for use in sutureless anastomosis between two hollow organs by means of an implantable anastomosis prosthesis and a prosthesis coupling device comprising:
- a targeting tube (14),
- a deployment tube (15) provided with a fastening device for cooperation with a fixation mechanism in the prosthesis coupling device, for fastening said prosthesis coupling device to said deployment tube (15),
- a flow control valve (52) for controlling fluid flow in and out of the apparatus, wherein the inlet (58) of the valve (52) is adapted for connection to a suction apparatus, and a first outlet (55) of the valve is coupled to a fluid connecting

device (57) adapted for connection to a corresponding tubing connection assembly (34) in the anastomosis coupling device (22),
- a flow control lever (53) for controlling flow through said valve (52), and
- a trigger (50) for displacing the deployment tube (15) in relation to the body of the apparatus,
- a device (59) for connecting the apparatus to a suction apparatus.

10. Apparatus according to claim 9,
characterised in that the fastening device consists of at least one fixation slot (18) extending from the edge (17b) of the deployment tube.

11. Apparatus according to claim 10,
characterised in that each fixation slot (18) comprises a long limb (74), a fixation fluke (75), a transverse limb (76) and a short limb (77),
where the fixation fluke (75) is meant for securing a fixation pin (60) in a fixation mechanism in the prosthesis coupling device (22) into the short limb (77) of the fixation slot (18).

12. Apparatus according to claim 10,
characterised in that each fixation slot (18) comprises a long limb (74), a transverse limb (76) and a short limb (77), where the short limb (77) is meant for receiving a fixation pin (60) in a fixation mechanism in the prosthesis coupling device (22).

13. Apparatus according to claim 9,
characterised in that the fastening device consists of at least one loop or hook polymer patch (66) arranged on the deployment tube (15) for fastening to a corresponding hook or loop pacth (67) in a fixation mechanism in the prosthesis coupling device (22).

14. Apparatus according to claim 9,
characterised in that the fastening device consists of at least one ferromagnetic patch (68) arranged on the deployment tube (15) for fastening to a corresponding magnet (69) in a fixation mechanism in the prosthesis coupling device (22).

15. Apparatus according to one of the preceding claims 9-14,
characterised in that it includes an inlet (70) for introduction of imaging or flow measuring devices.

16. Apparatus according to any of the preceding claims 9-15,
characterised in that a second outlet (54) of the flow control valve (52)

is coupled via a side arm (16) to the inside of the targeting tube (14) for transmitting a negative pressure to said targeting tube (14).

17. Apparatus according to one of the preceding claims, characterised in that it comprises a prosthesis coupling device according to one of claims 1-8 as an integrated element of the apparatus.

18. Anastomosis prosthesis comprising:
a first tubular member (1) attached to a flat member (2) wherein the prosthesis comprises a second tubular member attached to the first tubular member and adapted to act as instrument inlet.

Fig. 1

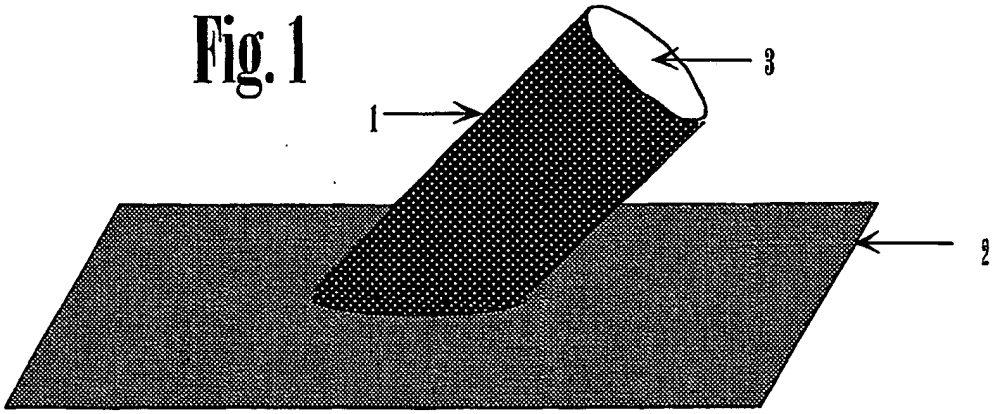


Fig. 2

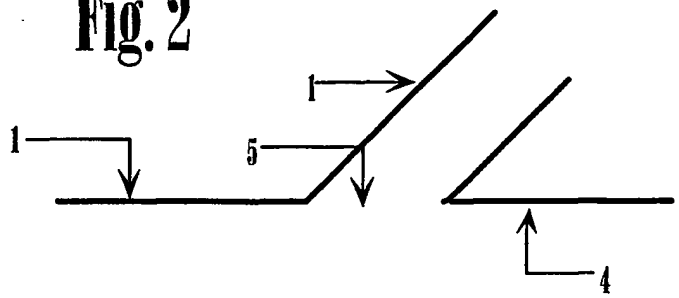


Fig. 3

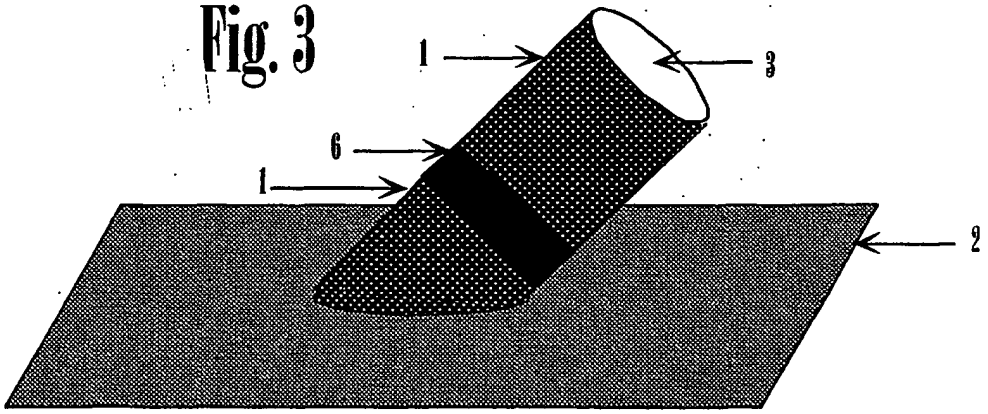


Fig. 4

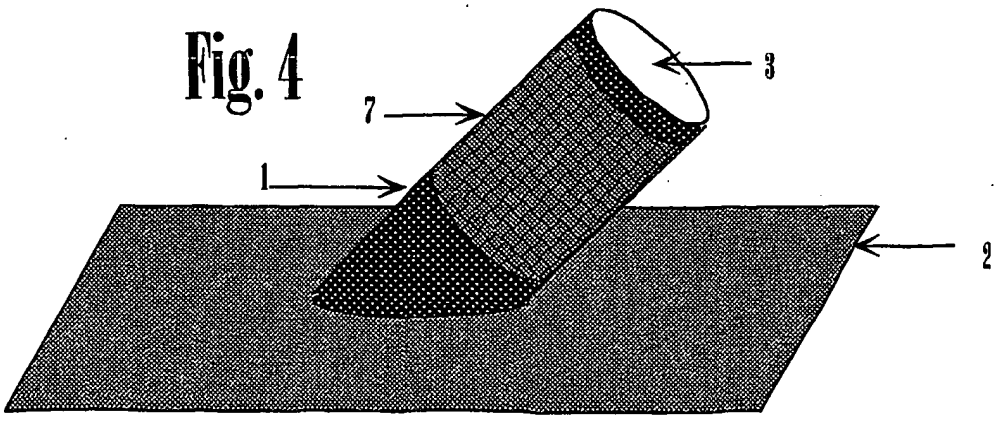


Fig. 5

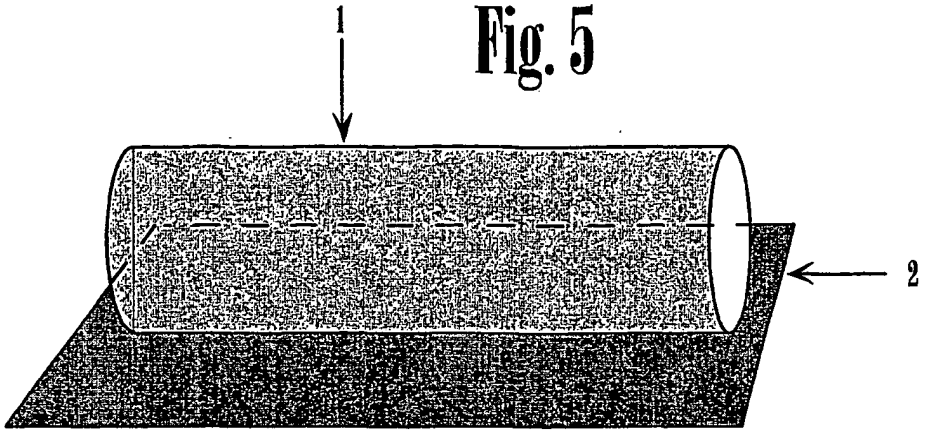


Fig. 6

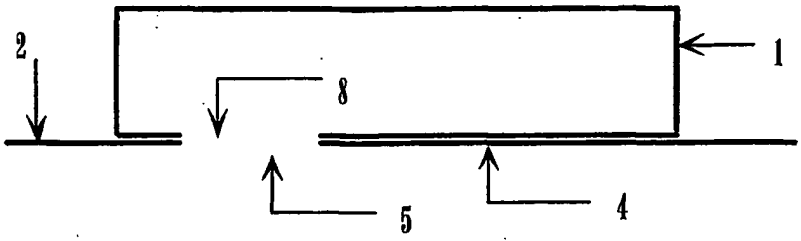


Fig. 7

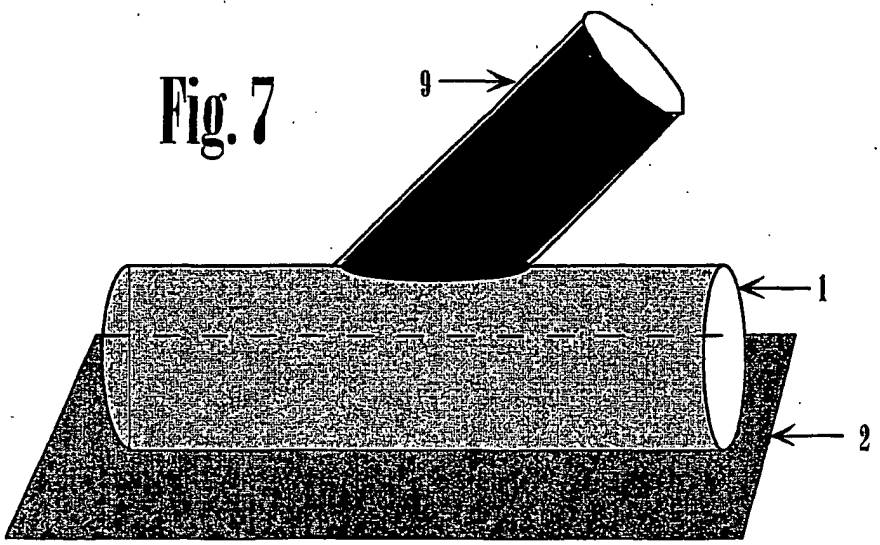
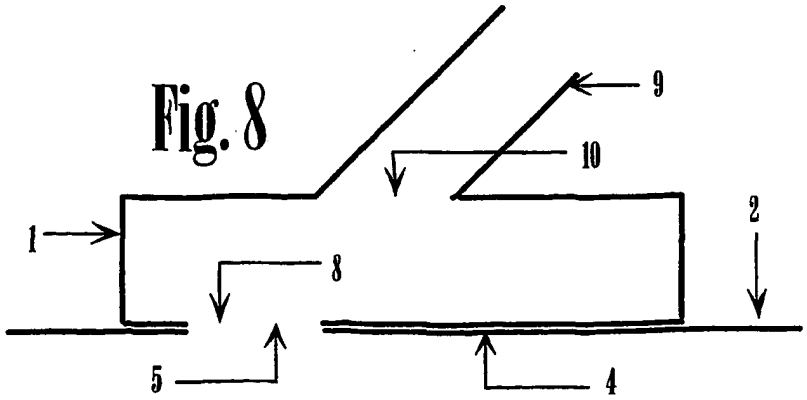


Fig. 8



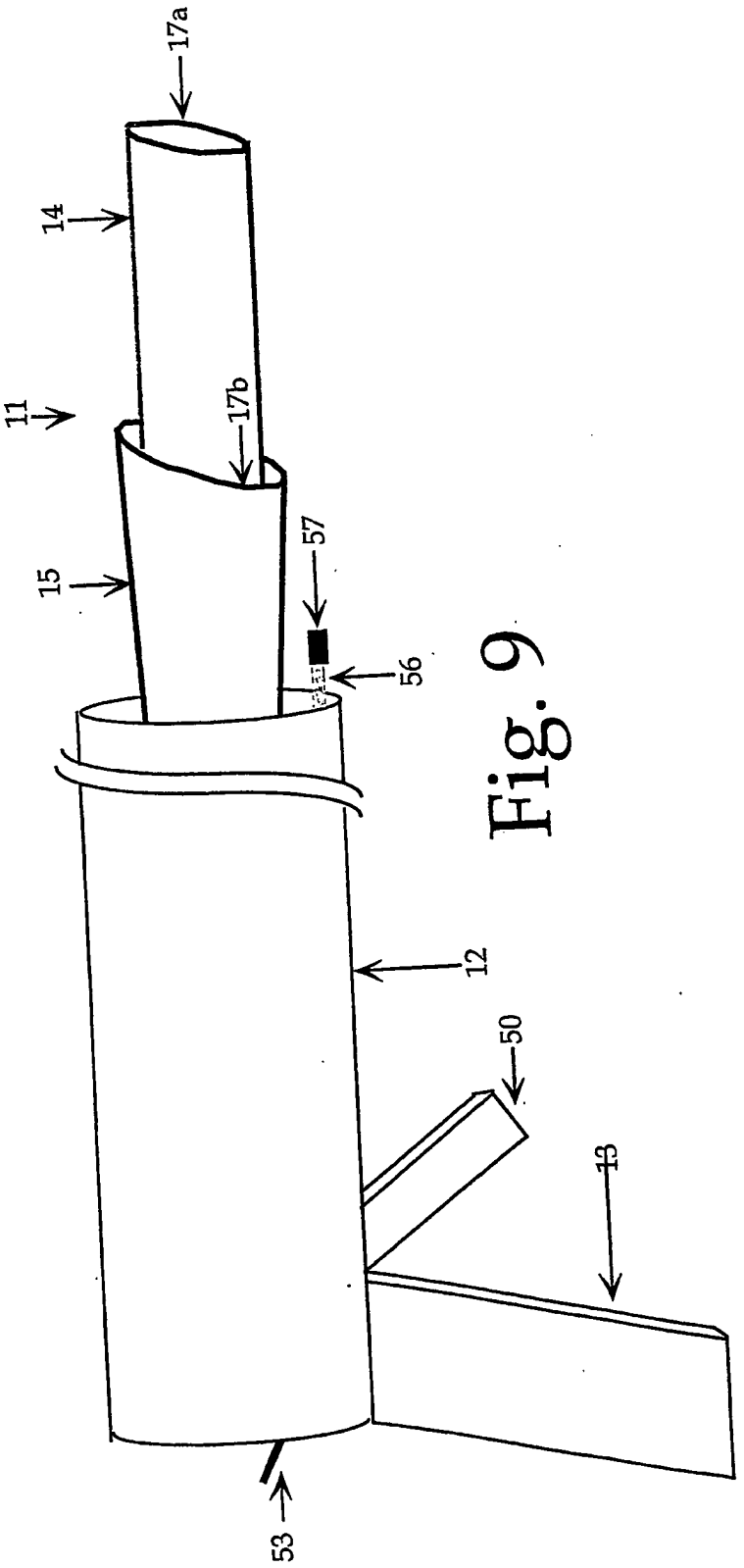


Fig. 9

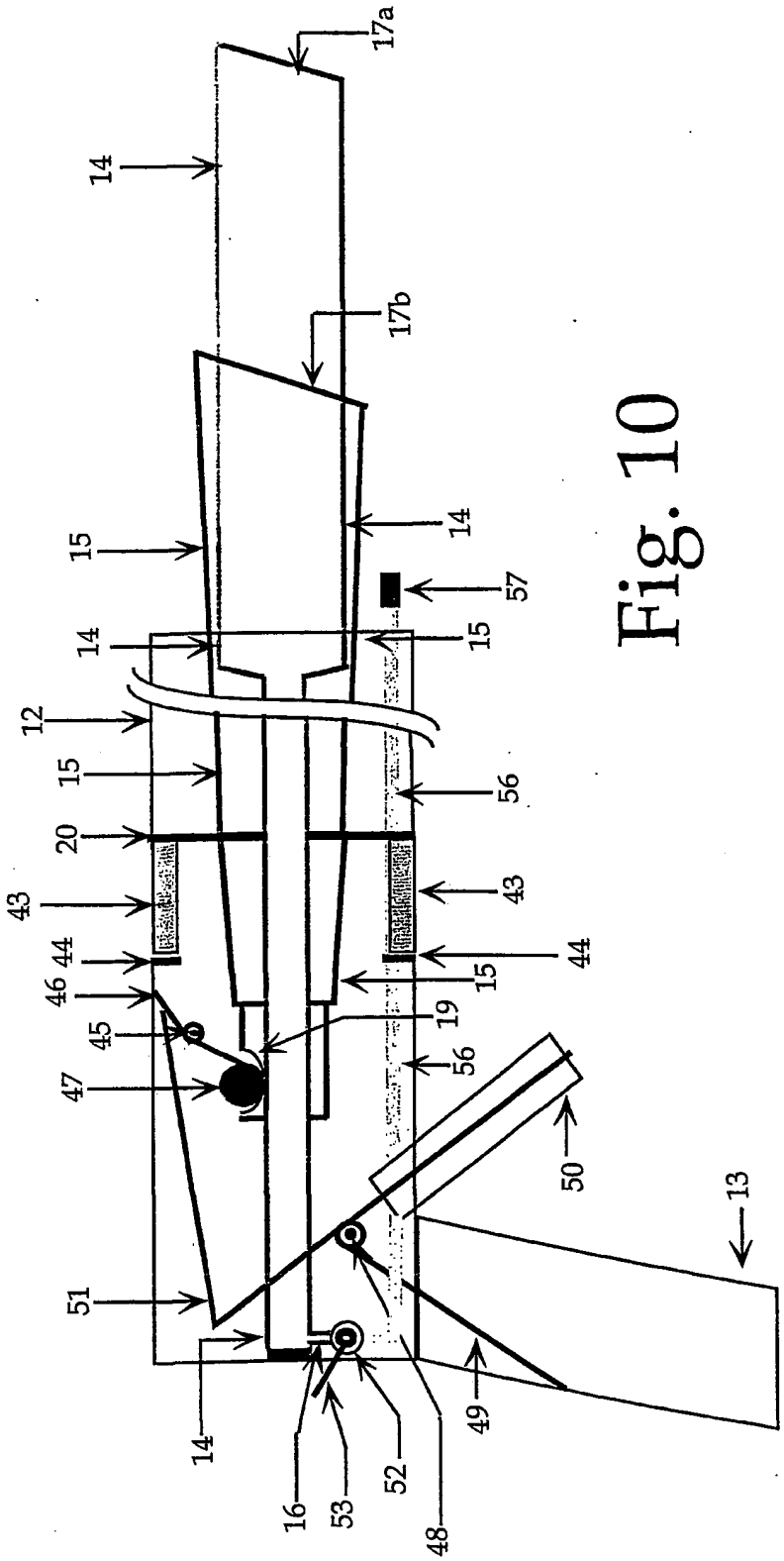

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Fig. 10

Fig. 11

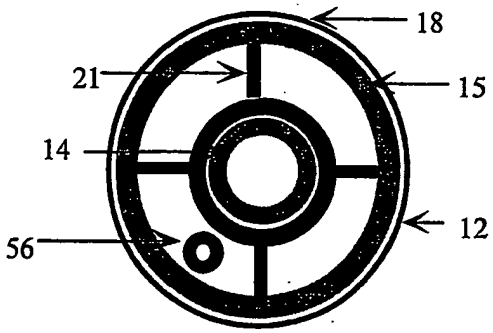


Fig. 12

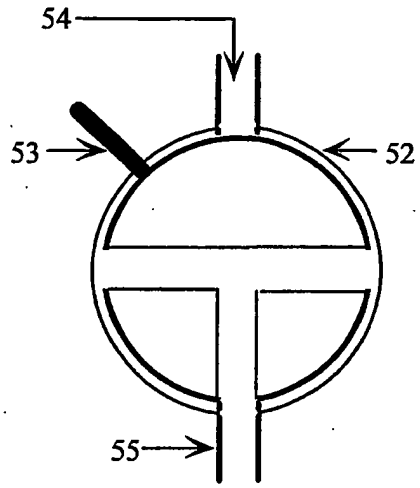
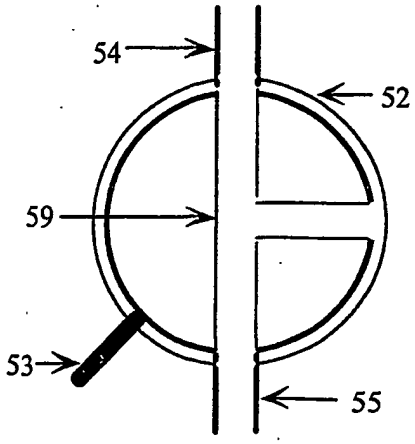


Fig. 13



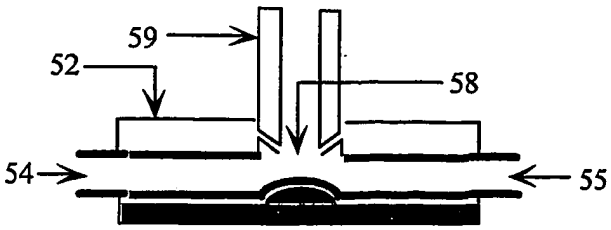


Fig. 14

Fig. 15

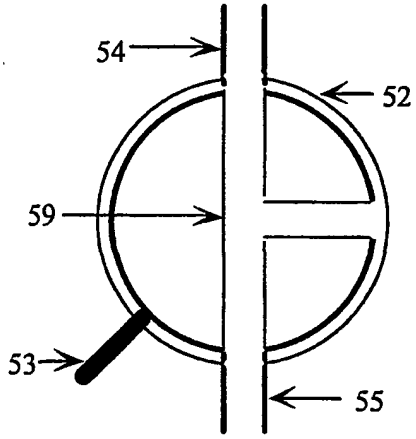


Fig. 16

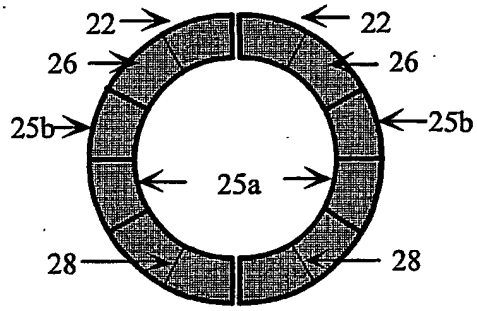
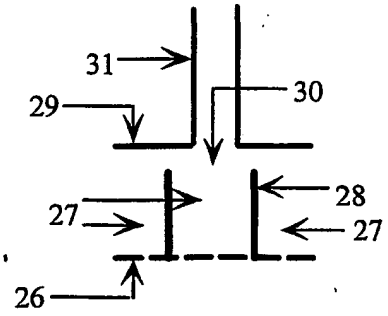


Fig. 17



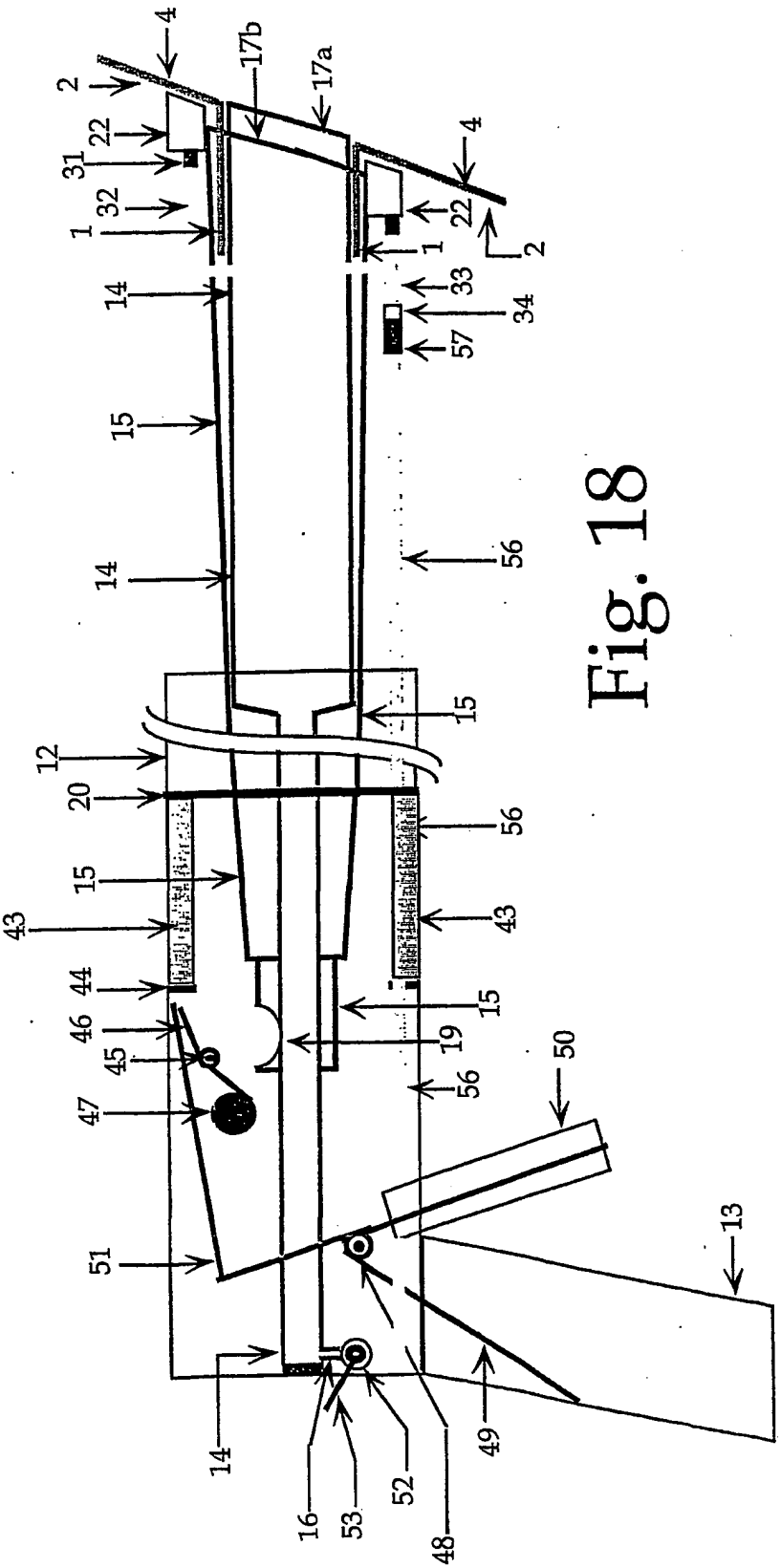

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Fig. 18

Fig. 19

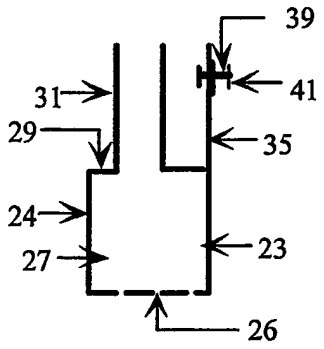


Fig. 20

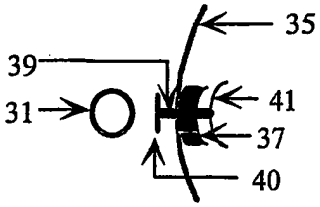


Fig. 21

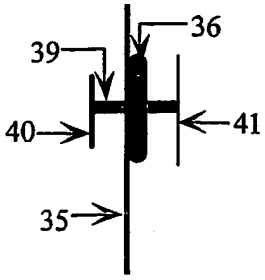


Fig. 22

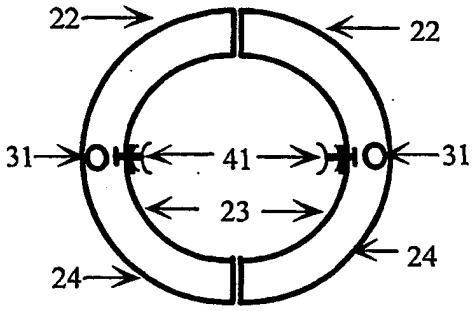


Fig. 23

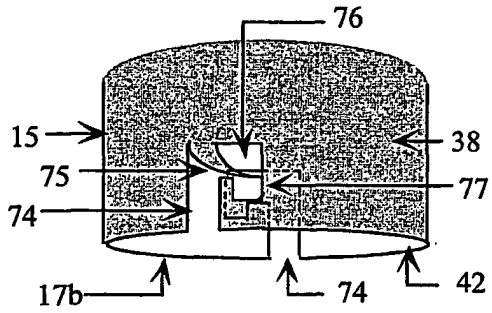


Fig. 24

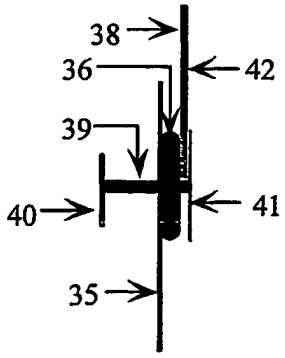
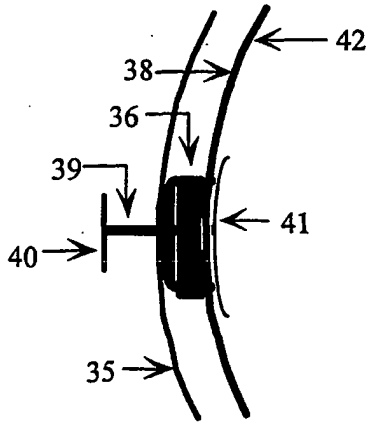


Fig. 25



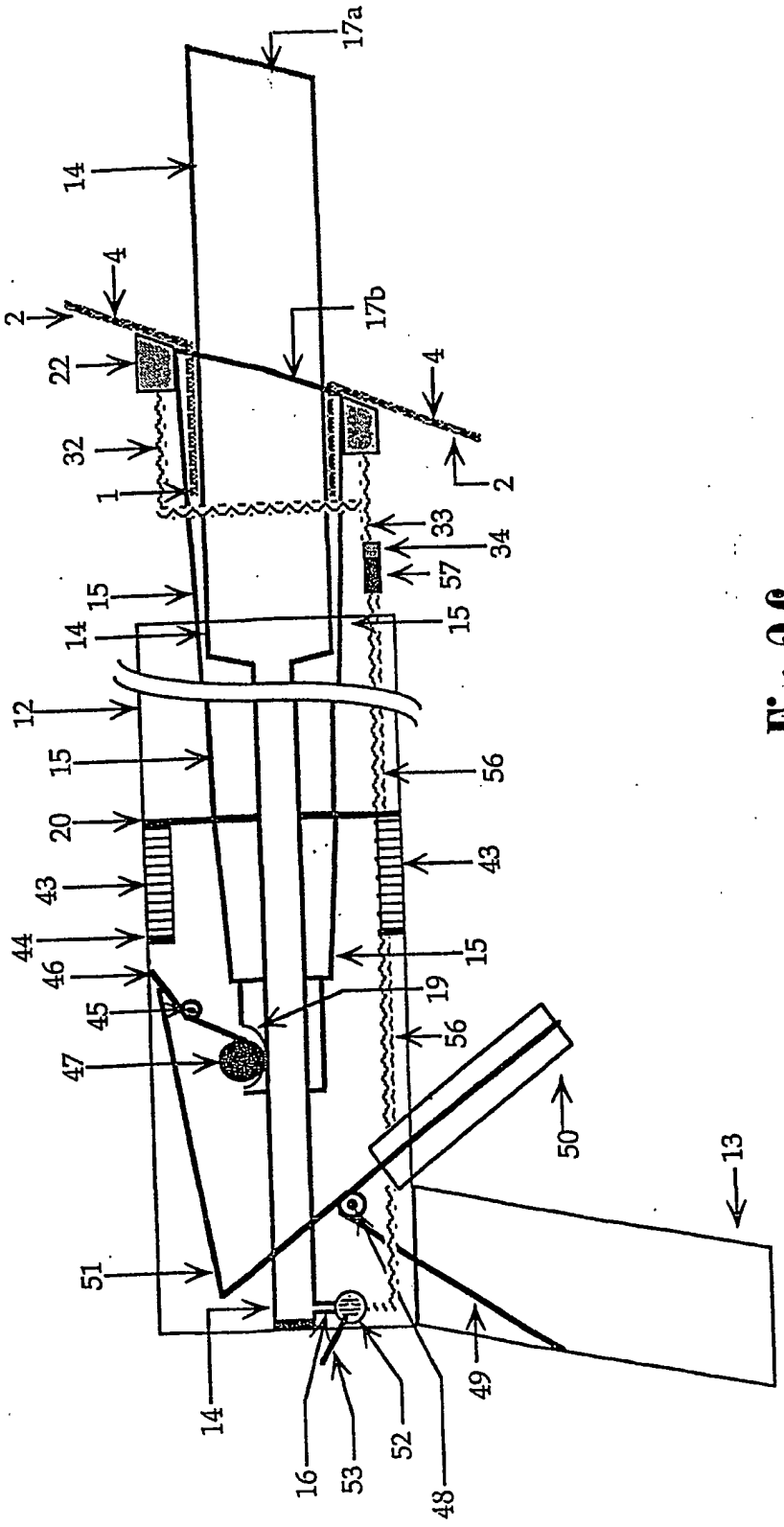

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Fig. 26

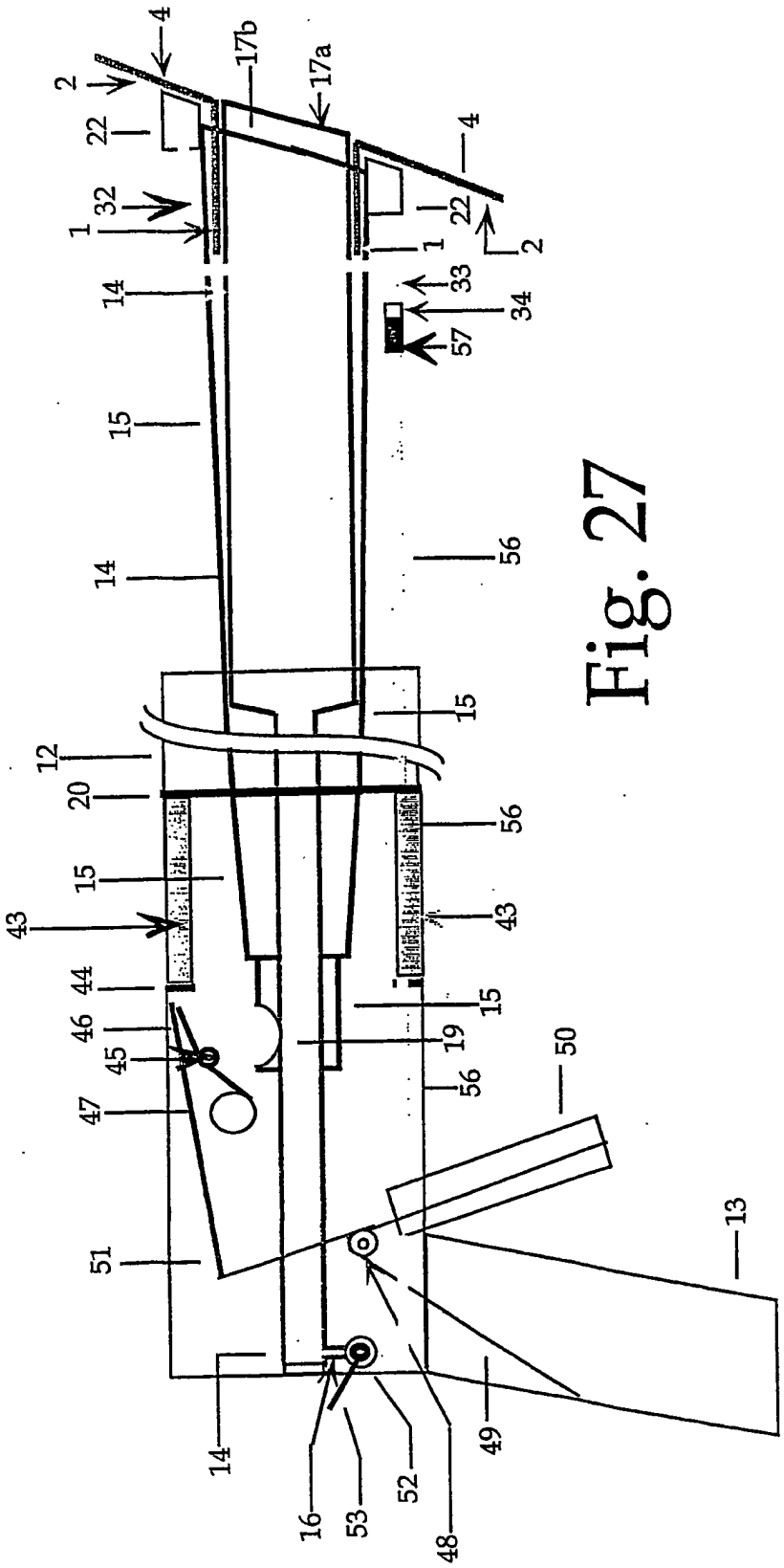
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Fig. 27

Fig. 28

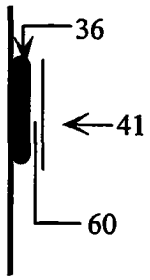

Fig. 29

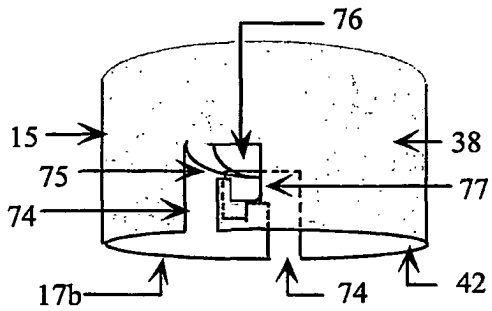

Fig. 30

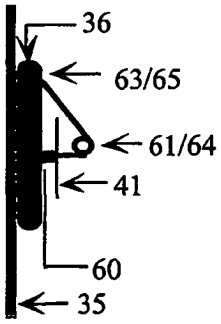

Fig. 31

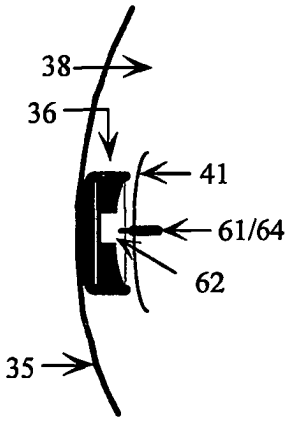

Fig. 32

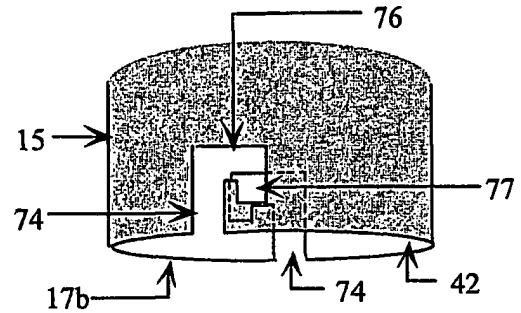

Fig. 33

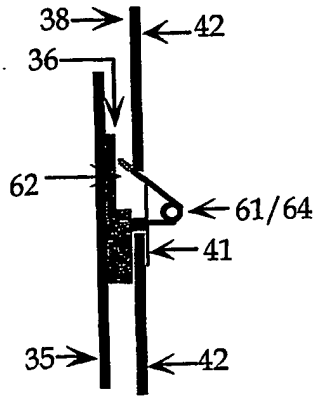

Fig. 34

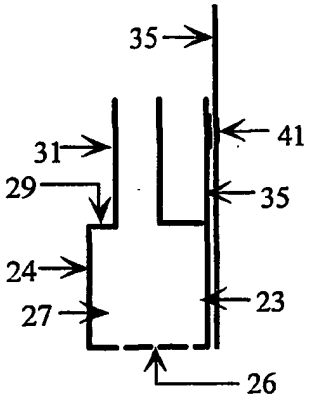

Fig. 35

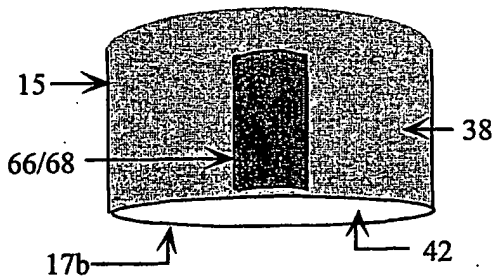

Fig. 36